

# Patent Law & Public Policy



### Interview with

**Lori Andrews, J.D.**

by Carol Blackburn

In this age of astonishing advances in biotechnological tools and discoveries, patent lawyers can hardly keep up with the demand for their services. But should we be patenting genes? Who considers the broader scientific and social impacts of our patent laws and policies? As the Director of the Institute of Science, Law and Technology at Illinois Institute of Technology's Chicago Kent School of Law, Professor Lori Andrews has taken a central role in this effort—in the classroom, the courtroom, and policy forums. *The National Law Journal* has named her one of the 100 Most Influential Lawyers in America. During her distinguished career, she has been a pioneer in numerous areas where law and science intersect. We focus here on the subject of gene patents.

### When did your interest in legal matters begin?

I was interested in consumer protection issues from an early age. When I was really young, my Ken doll went bald, and I wrote a letter to Mattel complaining. In high school, I was interested in writing about social issues. In college, I realized that to address some of the social policy issues that interested me, it would be useful to have a law degree.

### How did you become interested in biomedical issues in law?

I began my career at a time full of fascinating medical-legal issues—I passed the bar exam the day the first test-tube baby was born—and much of my work has concerned legal issues created by advances in reproductive technologies. That led to more general concerns about the increasing commodification of the human body. We're all excited by the promise of biotechnology—the prospect of being able to grow replacements for damaged or diseased tissues, or of having medicines tailored to our own individual biochemistry. But there is also a dark side to the burgeoning biotech industry: that our own cells and genes are now perceived by some as resources to be harvested and transformed into marketable commodities.

That may sound like hyperbole, but look at what's happening. In California, a doctor used cells from one of his patients, without the patient's knowledge or consent, and patented a cell line that he sold for millions of dollars. When the patient found out, he sued; but in a landmark decision, the California Supreme Court ruled 5 to 4 that the patient had no property right to his own body parts. That precedent still haunts us.

That doctor showed great inventiveness in noticing that his patient was producing an unusual compound and identifying the cell line that was producing it; and he deserves to be rewarded for that. But what about the patient's rights? We face this issue more generally in the area of patents on human genes because DNA from thousands of people was used in the sequencing of the human genome and in genetic mutation studies. Most of the work on the Human Genome Project (HGP) was financed with taxpayers' money. While we certainly want to reward the ingenuity and hard work that has made the biotech explosion possible, we need to make sure that the public gets a fair deal, too.

When the HGP began, no one thought scientists would own the genes they discovered. I chaired the HGP's national advisory group that dealt with ethical issues, and the pillars of the genetics community cautioned against patenting human genes. They thought scientists might not be willing to share data if they had a commercial interest in the genes they might discover.

### How did genes come to be patented?

The interest in encouraging innovation in the United States dates back to the Constitution, where there is an actual provision to create incentives for technological innovation.

Under that provision, Congress decided to award inventors a 20-year monopoly that allows an inventor to prevent anyone else from making, using, or selling that invention. Patents are considered a trade-off in which the public gets something new

in exchange for the monopoly granted the inventor.

To be patentable, an invention must meet certain criteria: it must be novel, non-obvious, and useful. Patent laws do not permit the patenting of products of nature or laws of nature because the public wouldn't be gaining anything new. The U.S. Supreme Court wrote that such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

However, in recent years, the U.S. Patent & Trademark Office started to grant patents on human genes. Their logic was that while a human gene as it occurs in nature cannot be patented, if a DNA sequence is purified, that "invention" is patentable.

### **That doesn't seem right.**

No, but there was a legal precedent for it. Courts have upheld patents on other purified natural products. However, I think their decision was inappropriate. The useful properties of a gene's sequence—its ability to encode a protein or to bind a complementary DNA strand in a diagnostic test—are inherent properties of the gene, not ones that scientists invented. I don't believe this is what the Founding Fathers envisioned; they thought it was very important for basic scientific information to be freely available.

Gene patents are part of a larger trend of patenting not just actual inventions and tangible things, but ideas. Until the 1980s, scientists patented what are called the "downstream" products of research, like drugs that inhibit a particular enzyme, or diagnostic assays that test for the presence of a particular molecule. The basic scientific information about those enzymes or molecules—the "upstream" discoveries about them—was open to all. This allowed different companies to develop different drugs that work at the same enzyme or different assays that test for the same molecule. This sort of competition has been of great benefit to the public, giving doctors and patients choices. Gene patents tie up that "upstream" information and get in the

way of future researchers using it.

I don't think the public or the research community is sufficiently engaged in a discussion of the implications of such changes. I helped found the Institute for Science, Law and Technology to create a forum for such discussion and study. One of my current projects is to look at what impact gene patents are having on biomedical research and health care.

### **What are some of the things you've found?**

Some consequences of gene patents are easy to see: instances where labs have discontinued promising avenues of research for fear of patent infringement, or where high fees for diagnostic testing have made those tests inaccessible to many people. For example, the company that holds the patent on the two genes most closely associated with breast cancer charges over \$2,500 for a genetic test of those genes; and they will not allow other doctors or laboratories to undertake those tests, even though the tests themselves could be done much less expensively. The company is taking advantage of its patent rights not only to charge whatever it likes for the test but also to forbid anyone else from looking at those two genes. One of the promises of the HGP was that people could be screened for mutations that raise their risk of developing cancer and other diseases. The technology now exists to screen thousands of genes in an efficient and economical way. But that clinical promise will not be realized if the fees are exorbitant. If looking at just two genes costs over \$2,500, the cost of screening 30,000 genes would be prohibitive.

Another consequence is that we see less collaboration among research institutions. The financial incentive *not* to share, *not* to collaborate, is a dramatic change from the era prior to gene patenting.

These impacts are easy to see. Others may not be as evident, but may be among the most profound. Gene patents threaten one of the most basic tenets of research: that independent researchers should be able

to verify your findings. If I patent a gene, I control whether anyone else can try to replicate my findings or verify my claims. Gene patents could also impede one of the great promises of genomic medicine: the use of diagnostic tests, rather than trial and error, to find the best drug for a given patient. If a drug manufacturer holds the patent on the gene sequence that tells whether that drug will be effective or not, he may just keep it locked up for 20 years so as not to lose some of the market for the drug.

### **Can a patent holder prevent research from being done by a university, not just a rival company?**

Yes. I've met many scientists who mistakenly think they are covered by a "research exemption." Copyright law includes various "fair use" exemptions where the public interest is involved, like allowing teachers to photocopy material for classes. But there are no such exemptions in U.S. patent law.

### **Tell us more about the patent process.**

The patent system is a three-way relationship among the Patent Office, the courts, and the Congress. At the Patent Office, the incentives favor the granting of patents: patent examiners receive a bonus when they close a file, and of course one way to do that is to grant the patent. It's important to understand that the Patent Office is not an investigative agency, like the Food & Drug Administration; it does not independently evaluate the claims made in patent applications.

### **Can Patent Office decisions be appealed?**

Unlike Europe, we don't have a formal system for doing that. However, the Patent Office can decide to re-examine its decisions. In the 1970s, when they first began granting patents on computer software, they didn't have patent examiners who were sufficiently knowledgeable about software, and they granted many overly broad patents.

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The Patent Office itself decided to review many patents and narrowed them.

More often, the courts or Congress are the ones to reduce the scope of patents. One of the most famous cases in U.S. patent law occurred when Samuel Morse convinced the Patent Office to grant him a patent on all uses of electromagnetic waves. A challenge to that patent went all the way to the U.S. Supreme Court, which ruled that Morse could not patent every conceivable use of electromagnetic waves; he could only patent his invention, the telegraph.

We're facing the problem of overly broad patents now, too. I have a grant from the U.S. Department of Energy's HGP and the Robert Wood Johnson Foundation to examine gene patents to see if any were granted inappropriately under the standards of current law. We have found patents that cover not only a gene but also any future discoveries or inventions by other people that concern that gene. So that company really has tied up the property rights to that gene well into the future, discouraging others from trying to study that gene or move the technology along.

### Have many gene patents been challenged in court?

One of the reasons we have runaway gene patents is that very few people are in a position to challenge gene patents. First of all, it's expensive; it would generally cost at least a half a million dollars to bring a patent challenge. Second, to bring a patent challenge, you must be an infringer upon that patent, not just a concerned citizen. The people most likely to infringe upon a gene patent are researchers or doctors. But most of them are in a bind. I've had lots of scientists call me and say, "We'd like to challenge this patent. We've been working on this gene for years and we think we're close to a cure, but now we've been shut down because the patent holder wants to be the one to discover the cure." But when they went to their university's lawyers, they were told, "You can't challenge this gene patent because we as a university have patents on other genes."

Most gene patent challenges have been between two parties to determine which one should get the patent; they haven't ques-

tioned the fundamental patentability of genes. The courts haven't yet heard a case in this area, so there is still a chance that the whole idea of gene patents could be thrown out. But no case like that is percolating up through the courts, so at this point, I think we're more likely to see legislative fixes. Congressman David Weldon, who is also a physician, is very interested in the impact of gene patents on health care policy and has introduced a bill that would create exemptions for the purposes of basic research and diagnostic testing.

The creation of patent pools—agreements in which a group of patent holders gather all the patents necessary to practice a certain technology in one place—could also improve the situation. An example of a patent pool is the American Society of Composers, Authors, and Publishers (ASCAP), which handles the licensing of music. Every time a radio station plays a song, it doesn't have to call up the composer and the lyricist and so on, and negotiate with each of them. Instead, radio stations pay a flat fee and can then use any song ASCAP covers. Such an arrangement could be created among gene patent holders, whereby researchers would pay a flat fee, then have the freedom to follow wherever their research led.

### Are law students exposed to these issues?

This has been fascinating for me. In every other area of law, you find law faculty who will argue different sides of an issue. That's not true in patent law. At the faculty level, there is surprisingly little back-and-forth on this subject. Other organizations have had to step in. For example, the American Association for the Advancement of Science (AAAS) now has a big project on the public-interest impacts of gene patents.

But among students, there is a lot of interest; in fact, two of my students recently won national awards for articles they published in this area. I think this is because we now have lots of students who majored in science, who worked in labs as undergraduates, and who have seen the effect gene patents have had on research. They started out thinking they would go into science and have ended up in law, and now want to help

create legal structures that will nurture science in appropriate ways.

### And where can they do that?

Some will do that as academics, others as policy advisors on Capitol Hill or for organizations like AAAS or the American Society of Human Genetics. There are many ways to be involved.

It's a really, really fascinating area of law, and an enormously important one. We're at a critical time in determining what we want from patent law, and what future scientists are going to be allowed to do. What we're really talking about is a battle over the future of science.

### For Further Reading

Learn more about Lori Andrews' work in her books *The Clone Age: Adventures in the New World of Reproductive Technology* and *The Body Bazaar: The Market for Human Tissue in the Biotechnology Age*.

For patent-law projects for high school students and links to additional resources on this topic, visit [cty.jhu.edu/imagine/links\\_114.htm](http://cty.jhu.edu/imagine/links_114.htm)



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